

### REMARKS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested. Claim 1 has been amended to correct the typographical error noted by the Examiner. Its entry does not require further search and would reduce the issues on appeal.

Claims 1 to 10 were rejected under 35 U.S.C. 112, first paragraph, as lacking written description because the Examiner alleges that the specification does not provide adequate support for 'human' E2F and 'human' P/CAF polypeptides as presently recited in the claims. Applicant traverses.

Contrary to the Examiner's assertion, the terms 'human' E2F (e.g., E2F1 to E2F5) and 'human' P/CAF are described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention as of the filing date of this application.

For example, page 19 of the specification describes nucleic acid encoding polypeptides of the invention (i.e., E2F and P/CAF polypeptides). The nucleic acid is described as being provided:

free or substantially free of material with which it is naturally associated, such as free or substantially free of nucleic acid flanking the gene in the human genome (emphasis added).

It is clear from the cited portion of the specification that Applicant has taught that his invention includes the use of human coding sequences (i.e., sequences encoding human polypeptides) and therefore human polypeptides.

Applicant also notes that the sequences of human E2F1 to E2F5 were known to the skilled person at the time this application was filed (see, for example, the database accession numbers AAA35782.1, AAA16890.1, CAA71504.1, AAC50119.1 and CAB01634.1, respectively). Therefore, the general knowledge in the art included the sequences which the Examiner alleged were missing from the specification. A specification need not teach, and preferably omits, what is well known in the art. See *Hybritech v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986).

The specification also describes target sequences of E2F as human sequences. For example, page 38 of the specification describes suitable promoters for use in the invention. A promoter with a human target sequence is exemplified:

An example of a suitable promoter is that of the human cyclin E gene, a relevant biological target of E2F1. There is evidence that activation of this promoter by E2F1 is required by for cell cycle progression (emphasis added).

In describing target sequences, the specification is clearly contemplating human E2F polypeptides which bind to cognate target sequences in human genes. It is clear from this portion of the specification that Applicant has taught that his invention includes the use of human target sequences.

Furthermore, the acetylation of human E2F by human P/CAF is exemplified in the Experimental section. Experiments 2-3 (pages 62-64 of the specification) describe mutants of human E2F1 and indicate that the GST-E2F-1 deletion constructs used in Experiment 1 contained human E2F1 sequences. Experiments 4-5 and 9 (pages 64-65 and 68-69 of the specification) are performed on human cell lines U205 and 293T, which clearly express human E2F polypeptides. Thus, experiments 1-5 and 9 are clearly directed at human E2F proteins. It is therefore not reasonable for the Examiner to assert that the specification does not contemplate human E2F and P/CAF polypeptides – human polypeptides were clearly foremost in the Applicant's mind and within the scope of his claimed invention.

Finally, the references incorporated in the specification confirm that human E2F and P/CAF polypeptides were contemplated by the inventor:

Yang et al. (Nature 382 319-324, 1996) was cited in the specification on page 6, lines 5-6. This reference describes the cloning of P/CAF from a human cDNA library (page 319, 2<sup>nd</sup> column, 3<sup>rd</sup> paragraph)(emphasis added). The P/CAF disclosed in this reference is therefore human P/CAF. As Yang et al. is incorporated into the specification by reference on page 61, lines 23-24, it is clear that the specification specifically contemplates human P/CAF.

Tao et al. (Mol. Cell. Biol. 17:6994-7007, 1997) was cited in the specification on page 38, lines 21-22. This reference describes the use of human E2F cDNA (page 6995, col. 2). Tao et al. is incorporated into the specification by reference on page 61,

lines 23-24, and so it is clear that the specification specifically contemplates human E2F polypeptides.

Ohtani et al. (Proc. Natl. Acad. Sci. USA 92:12146-12150, 1995) was cited in the specification on page 39, line 1. This reference cross references the use of AdE2F1 (page 12147, 1<sup>st</sup> column) from Schwartz et al. (Proc. Natl. Acad. Sci. USA 92:483-487, 1995). This recombinant adenovirus expresses the human E2F1 protein. As Ohtani et al. is incorporated into the specification by reference on page 61, lines 23-24, it is clear that the specification specifically contemplates human E2F polypeptides.

The disclosure of the specification and the documents incorporated by reference clearly rebut the allegation that the specification does not contemplate the use of human E2F1 to E2F5 and human P/CAF polypeptides. It is clear from the above that the specification specifically contemplates human P/CAF and human E2F1 to E2F5 and one of skill in the art would reasonably conclude that the skilled person was in possession of assay methods which employ human P/CAF and human E2F polypeptides as presently claimed.

Withdrawal of the Section 112 rejection is therefore requested.

Having fully responded to all of the pending objections and rejections contained in the Office Action (Paper No. 20) Applicant submits that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

Gary R. Tanigawa  
Reg. No. 43,180

1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100